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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,510	03/06/2001	Brett Cowan	3652-33	1367
23117	7590	03/13/2006	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			LU, TOM Y	
			ART UNIT	PAPER NUMBER

2621

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/786,510	<b>Applicant(s)</b> COWAN ET AL.	
	<b>Examiner</b> Tom Y. Lu	<b>Art Unit</b> 2621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 82-112 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 82-112 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

1. The amendment and written response filed on 12/16/2005 has been entered and considered.
2. Claims 1-81 were cancelled.
3. Claims 82-112 are newly added.
4. Claims 82-112 are pending.

### ***Response to Arguments***

5. Upon entry of the amendment, the claims 1-81 have been cancelled, and the rejection of these cancelled claims has been withdrawn accordingly.

### ***Claim Objections***

6. Claim 91 is objected to because of the following informalities: two claims are numbered as 91. For the purpose of examination, the examiner has renumbered the second claim 91 as claim 92. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 102-111 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Since a computer program is merely a set of instructions capable of being executed by a computer, the computer program itself is not a process and Office personnel should treat a claim for a computer program, without the computer-readable medium needed to realize the computer program's functionality, as nonstatutory

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functional descriptive material. When a computer program is claimed in a process where the computer is executing the computer program's instructions, Office personnel should treat the claim as a process claim. When a computer program is recited in conjunction with a physical structure, such as a computer memory, Office personnel should treat the claim as a product claim.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 82-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan et al (U.S. Patent No. 6,106,466) in view of Branham et al (U.S. Patent No. 5,687,737).

- a. Referring to Claim 82, Sheehan discloses a method of accessing one or more characteristics of an organ or part thereof from multiple images acquired of the organ or part thereof, the method including forming a fit between a reference model of the geometric shape of the organ or part thereof and a series of acquired images of the organ or part thereof by a series of user interactive steps which consist essentially of: defining the spatial position of at least two of the acquired images (Sheehan at column 8, lines 64-66, teaches "the time varying position and orientation of the ultrasound transducer relative to magnetic field generator 68 comprise data that are stored in a non-volatile memory", such position data is spatial position data, which defines the position of the ultrasound transducer at the time each

image frame is recorded by the CPU and thereby enable the CPU to compute the three-dimensional coordinates, column 9, lines 3-7); forming an initial fit between the reference model and the acquired images by displaying one or more of the acquired images to a user, manually user defining one or more reference markers on the acquired images, and initially fitting the model to the acquired images by reference to the reference markers on the images (Sheehan at column 12, line 9, discloses a mesh model of an archetype heart, which is the claimed “reference model”. Note Sheehan at column 13, line 3-6, teaches abstract mesh model is used for initial fitting; column 13, lines 8-9, anatomic landmarks are the claimed “reference markers”; Sheehan teaches manually selecting an imaging plane for tracing at column 13, line 28-29); displaying to a user an acquired image of the subject organ or art thereof, the image including at least one organ boundary derived from the intersection of a surface of the organ with the plane of the image (figure 3); displaying to the user a representation of the initial fit of the reference model by displaying on the acquired image a representation of the intersection of the model with the plane of the image (predicted image is the claimed “a representation of the intersection of the model”, see figure 12 for displaying); Sheehan discloses automatically performing fitting of the predicted images derived from the model with the patient’s images by comparing the predicted images and the patient’s images, column 15, lines 13-15 and 23-24, which forces the mesh model to adjust the vertices to match the corresponding feature boundaries on each image of the patient’s heart, column 16, lines 12-13. In forcing the control vertices of the mesh boundaries, the boundary points on each image of the patient’s heart are

converted from (x, y) to (x, y, z) coordinates, column 11, lines 65-67. Sheehan also notes the fitting process needs to be performed on a plurality of images of the patient's heart to provide an optimized fitting between the mesh model and the patient's heart. However, Sheehan's fitting process is an automatic process, and does not require an user manually define reference guide points on a user selected organ boundary on the image displayed to the user. The examiner notes Sheehan at column 17, lines 35-40, teaches if the automatic fitting process does not produce a satisfactory result, an user may want to manually edit the abstract mesh of the mesh model for each image of the patient's heart. Although, Sheehan does not explicitly state the editing steps, it is well known in the art in order to perform the match between a patient's heart image and the mesh model, reference guild points need to be defined manually. Brandham teaches in adjusting a standard mesh model to provide a closer approximation, column 17, lines 1-2, a user needs to manually defines the marker points as shown in figures 2A to 2B. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify Sheehan's system with Brandham's manually editing technique because Sheehan already recognizes it is an option for an user to manually editing the abstract mesh model to provide a better fitting, column 17, lines 35-38, and Brandham additionally points out such manually editing process is not very time consuming, column 18, lines 32-33, and it would provide a better approximation, column 17, line 1.

- b. Referring to Claim 83, Sheehan discloses forming the initial fit between the reference model and the images by defining a point on each of two images, defining a reference line in 3-dimensional space between the point, calculating the distance as a function of the length of the reference line, and at least approximately matching the scale of the reference model and the images according to the distance between the points (Sheehan in figure 13, block 230, teaches mesh model rigidly aligned and scaled to match image data at 3 landmark points, and see the central axis in figure 6 for so-called “reference line”).
- c. Referring to Claim 84, Sheehan discloses wherein the reference model comprises a mathematically defined reference model (Sheehan at column 12, lines 8-11, teaches the reference model is a mathematically defined reference model).
- d. Referring to Claim 85, Sheehan discloses wherein the reference model comprises an ellipsoid having the reference line as a central axis and one or more surface points, each surface point specified by a radial distance from the central axis (see figure 6).
- e. Referring to Claim 86, Sheehan discloses the step of performing image processing on one or more of the images (column 14, lines 64-66).
- f. Referring to Claim 87, Sheehan discloses the step of calculating the volume of the subject organ or part from the estimate model (column 17, lines 45-47).
- g. Referring to Claim 88, Sheehan discloses the step of calculating the mass of the subject organ or part from the estimate model (column 17, lines 45-47).
- h. Referring to Claim 89, Sheehan discloses wherein the subject organ comprises a ventricle of the heart and the characteristics measured include ventricular mass,

endocardial volume and/or wall thickness of all of the ventricle or part thereof (column 17, lines 45-47).

- i. Referring to Claim 90, Sheehan discloses wherein the subject organ comprises a ventricle of the heart and the characteristics measured include ventricular abnormalities identified through changes in a wall thickness over time (Sheehan at abstract teaches the imaging processing is carried out over at least one cardiac cycle, which allows user to define any ventricular abnormalities identified through changes in wall thickness over time).
- j. Referring to Claim 91, Sheehan discloses wherein the subject organ comprises a kidney and the characteristics measured included cortical thickness (Sheehan at column 9, lines 35-36, teaches his system is applicable to other organs in the patient's body, and a kidney is an organ).
- k. With regard to Claim 92, the combination of Sheehan and Brandham teaches the image processing system is a computer system, which inherently includes all the means for implementing the processing steps recited in Claim 92. The functional steps are explained in Claim 82.
- l. With regard to Claim 93, see explanation in Claim 83.
- m. Referring to Claim 94, the mesh model in Sheehan is a finite element model.
- n. With regard to Claim 95, see explanation in Claim 85.
- o. With regard to Claim 96, see explanation in Claim 86.
- p. With regard to Claim 97, see explanation in Claim 87.
- q. With regard to Claim 98, see explanation in Claim 88.
- r. With regard to Claim 99, see explanation in Claim 89.



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- s. With regard to Claim 100, see explanation in Claim 90.
- t. With regard to Claim 101, see explanation in Claim 91.
- u. With regard to Claim 102, the examiner notes as explained above the image processing system in Sheehan is a computer system, which inherently includes a computer program stored on a computer medium.
- v. With regard to Claim 103, see explanation in Claim 93.
- w. With regard to Claim 104, see explanation in Claim 94.
- x. With regard to Claim 105, see explanation in Claim 95.
- y. With regard to Claim 106, see explanation in Claim 96.
- z. With regard to Claim 107, see explanation in Claim 97.
- aa. With regard to Claim 108, see explanation in Claim 98.
- bb. With regard to Claim 109, see explanation in Claim 99.
- cc. With regard to Claim 110, see explanation in Claim 100.
- dd. With regard to Claim 111, see explanation in Claim 101.
- ee. With regard to Claim 112, the examiner notes the computer system in Sheehan contains a computer readable medium.

### ***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tom Y. Lu whose telephone number is (571) 272-7393. The examiner can normally be reached on 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jingge Wu can be reached on (571)-272-7429. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tom Y. Lu

JINGGE WU  
PRIMARY EXAMINER

